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10/586,045	06/12/2007	Jung-Hoon Sohn	2472.0010000/EKS/RAS	2495

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WASHINGTON, DC 20005

EXAMINER

STEELE, AMBER D

ART UNIT	PAPER NUMBER
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1639

MAIL DATE	DELIVERY MODE
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11/16/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/586,045	Applicant(s) SOHN ET AL.	
	Examiner AMBER D. STEELE	Art Unit 1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on September 8, 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18-71 is/are pending in the application.
- 4a) Of the above claim(s) 21, 24, 35-37, and 39-71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20, 22, 23, 25-34, and 38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on July 14, 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>3/20/08</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Status of the Claims

1. Claims 1-17 were originally filed on July 14, 2006.

The preliminary amendment received on July 14, 2006 canceled claims 1-17 and added new claims 18-71.

Claims 18-71 are currently pending.

Claims 18-20, 22, 23, 25-34, and 38 are currently under consideration.

Election/Restrictions

2. Applicants' election with traverse of Group I (claims 18-38) in the reply filed on September 8, 2009 is acknowledged. The traversal is on the ground(s) that a serious search burden does not exist. This is not found persuasive because the present application is a 371 (National Stage) application and restriction is deemed proper based on Lack of Unity (see 37 CFR 1.475). The search burden is part of the requirement for U.S. restriction practice (see MPEP § 803). Since applicants have not traversed the Lack of Unity, the restriction is deemed proper.

The requirement is still deemed proper and is therefore made FINAL.

3. Claims 39-71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 8, 2009.

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4. Applicant's election with traverse of human IL-2 as the species of target protein, yeast genomic DNA as the species of source and type of polynucleotide, *S. cerevisiae* as the species of cell, invertase as the species of reporter, and automatic screening vector comprising Gal10 promoter as the species of screening vector in the reply filed on September 8, 2009 is acknowledged. The traversal is on the ground(s) that a serious search burden does not exist. This is not found persuasive because the present application is a National Stage (i.e. 371) application and is not bound by U.S. restriction practice (i.e. MPEP § 803). In addition, the species are all structurally and/or functionally different. A search of methods utilizing polynucleotides from microorganisms would not be coextensive with a search for methods utilizing polynucleotides from plants, etc. If applicants believe that all species are obvious variants of each other, applicants are respectfully requested to state that the species are all obvious variants clearly on the record.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 21, 24, and 35-37 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on September 8, 2009.

Priority

6. The present application claims status as a National Stage (371) of PCT/KR04/03517 filed December 30, 2004. The present application also claims foreign priority to KR 10-2004-0003610 filed January 17, 2004 and KR 10-2004-0003957 filed January 19, 2004.

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7. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

8. It is noted that translations for KR 10-2004-0003610 and KR 10-2004-0003957 were not provided. Therefore, applicants may not receive the full benefit of the foreign priority documents. See 37 CFR 1.55 and MPEP § 201.15.

Information Disclosure Statement

9. The information disclosure statement (IDS) submitted on March 20, 2008 is being considered by the examiner. Regarding the search reports, unless the references referred to in the search reports were listed separately in the IDS and copies provided if necessary, the references were not considered.

Specification

10. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

12. Claims 18-20, 22, 23, 25-34, and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. One of skill in the art would not be able to determine

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the scope of the presently claimed invention. For example, is the polynucleotide encoding a target protein of method step (a) the same as (at least one of) the polynucleotide fragments of method step (b)? What is the TFP comprised of? Is the TFP a fusion of target protein and reporter protein? Does the TFP include anything that the polynucleotide fragments encode? What is the purpose of the polynucleotide fragments if they are not analyzed for in the method?

Claim Rejections - 35 USC § 102

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 18, 19, 23, 25, 28-33, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al. U.S. Patent 6,136,569 issued October 24, 2000.

For present claims 18, 19, 23, 25, 28-33, and 38, Baker et al. teach methods comprising preparing vectors via fusing a reporter gene (i.e. encoding a reporter protein) including invertase or amylase in frame with signal sequences, and genomic DNA fragments, transforming the vectors into *S. cerevisiae* which do not have active reporter genes, culturing cells including culturing cells on media containing only sucrose as a carbon source (i.e. for invertase) or starch (i.e. for amylase), identifying reporter protein activity, and isolating secreted polypeptides encoded by the polynucleotide fragments (please refer to the entire specification particularly the abstract; Figures 1-3; columns 1-7 and 10-11).

Therefore, the teachings of Baker et al. anticipate the presently claimed method.

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15. Claims 18, 19, 23, 25, 28-33, and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker et al. WO 99/49028 published September 30, 1999 (provided by applicants in the IDS).

For present claims 18, 19, 23, 25, 28-33, and 38, Baker et al. teach methods comprising preparing vectors via fusing a reporter gene (i.e. encoding a reporter protein) including invertase or amylase in frame with signal sequences, and genomic DNA fragments, transforming the vectors into *S. cerevisiae* which do not have active reporter genes, culturing cells including culturing cells on media containing only sucrose as a carbon source (i.e. for invertase) or starch (i.e. for amylase), identifying reporter protein activity, and isolating secreted polypeptides encoded by the polynucleotide fragments (please refer to the entire specification particularly the abstract; Figures 1-3; pages 1-4, 6-13, 16, 17).

Therefore, the teachings of Baker et al. anticipate the presently claimed method.

Claim Rejections – 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 18-20, 22, 23, 25-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. U.S. Patent 6,136,569 issued October 24, 2000; Baker et al. U.S. Patent 5,212,058 issued May 18, 1993; and Black et al. U.S. Patent 5,547,871 issued August 20, 1996.

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For present claims 18, 19, 23, 25, 28-33, and 38, Baker et al. teach methods comprising preparing vectors via fusing a reporter gene (i.e. encoding a reporter protein) including invertase or amylase in frame with signal sequences, and genomic DNA fragments, transforming the vectors into *S. cerevisiae* which do not have active reporter genes, culturing cells including culturing cells on media containing only sucrose as a carbon source (i.e. for invertase) or starch (i.e. for amylase), identifying reporter protein activity, and isolating secreted polypeptides encoded by the polynucleotide fragments (please refer to the entire specification particularly the abstract; Figures 1-3; columns 1-7 and 10-11).

However, Baker et al. does not specifically teach human IL-2, yeast DNA libraries, or a Gal10 promoter.

For present claims 26, 27, and 34, Baker et al. teach methods of making fusion polypeptides comprising producing yeast gDNA fragment libraries and utilizing Gal10 promoter in expression vectors (please refer to the entire specification particularly Examples 1 and 2).

For present claims 20 and 22, Black et al. teach methods of making fusion proteins including utilizing human IL-2 signal sequence (please refer to the entire specification particularly columns 6 and 7).

The claims would have been obvious because the substitution of one known element (i.e. genus of genomic DNA library, genus of promoter, and genus of secretion signals or fusion proteins as taught by Baker et al.) for another (i.e. species of yeast gDNA library and species of Gal10 promoter taught by Baker et al. and species of human IL-2 taught by Black et al.) would have yielded predictable results (i.e. screening for secreted yeast polypeptides encoded by yeast gDNA, polypeptide expression in yeast via Gal10 promoter in vectors, and secretion) to one of

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ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

18. Claims 18-20, 22, 23, 25-34, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. WO 99/49028 published September 30, 1999 (provided by applicants in the IDS); Baker et al. U.S. Patent 5,212,058 issued May 18, 1993; and Chung et al. U.S. Patent 5,712,113 issued January 27, 1998.

For present claims 18, 19, 23, 25, 28-33, and 38, Baker et al. teach methods comprising preparing vectors via fusing a reporter gene (i.e. encoding a reporter protein) including invertase or amylase in frame with signal sequences, and genomic DNA fragments, transforming the vectors into *S. cerevisiae* which do not have active reporter genes, culturing cells including culturing cells on media containing only sucrose as a carbon source (i.e. for invertase) or starch (i.e. for amylase), identifying reporter protein activity, and isolating secreted polypeptides encoded by the polynucleotide fragments (please refer to the entire specification particularly the abstract; Figures 1-3; pages 1-4, 6-13, 16, 17).

However, Baker et al. does not specifically teach human IL-2, yeast DNA libraries, or a Gal10 promoter.

For present claims 26, 27, and 34, Baker et al. teach methods of making fusion polypeptides comprising producing yeast gDNA fragment libraries and utilizing Gal10 promoter in expression vectors (please refer to the entire specification particularly Examples 1 and 2).

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For present claims 20, 22, and 34, Chung et al. teach methods of making fusion proteins including utilizing human IL-2 and Gal10 promoters (please refer to the entire specification particularly the abstract; Figures 1, 5, and 6; columns 3 and 5).

The claims would have been obvious because the substitution of one known element (i.e. genus of genomic DNA library, genus of promoter, and genus of secretion signals or fusion proteins as taught by Baker et al.) for another (i.e. species of yeast gDNA library and species of Gal10 promoter taught by Baker et al. and species of human IL-2 and species of Gal10 promoter taught by Chung et al.) would have yielded predictable results (i.e. screening for secreted yeast polypeptides encoded by yeast gDNA, polypeptide expression in yeast via Gal10 promoter in vectors, and secretion) to one of ordinary skill in the art at the time of the invention. See *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385 (U.S. 2007).

Double Patenting

19. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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20. Claims 18-20, 22, 23, 25-34, and 38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4, 11-17, 21-25, 33-35, 39-42, 45-47, 50-51, 54-55, 72, 74, 76-80, 86, 91, 97, 100, 105, 109, 114, 117, and 119 of copending Application No. 11/914,437. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the presently claimed methods and the methods as claimed in 11/914,437 are drawn to methods of identifying a TFP.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Future Communications

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMBER D. STEELE whose telephone number is (571)272-5538. The examiner can normally be reached on Monday through Friday 9:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Amber D. Steele/
Primary Examiner, Art Unit 1639